

(7) Require that individuals with access approval from the Administrator or the HHS Secretary immediately report any of the following to the responsible official:

- (i) Any loss or compromise of keys, passwords, combinations, etc.;
 - (ii) Any suspicious persons or activities;
 - (iii) Any loss or theft of select agents or toxins;
 - (iv) Any release of a select agent or toxin; and
 - (v) Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised; and
- (8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) In developing a security plan, an individual or entity should consider the document entitled, "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents," in *Morbidity and Mortality Weekly Report* (December 6, 2002); 51 (No. RR-19):1-6. This document is available on the Internet at <http://www.cdc.gov/mmwr>.

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.⁹ The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

⁹Technical assistance and guidance may be obtained by contacting APHIS.

(c) In developing a biosafety plan, an individual or entity should consider the following:

(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories." This document may be obtained from the U.S. Government Printing Office. It is also available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR 1910.1200 and 1910.1450.

(3) The "NIH Guidelines for Research Involving Recombinant DNA Molecules." This document is available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

§ 121.13 Restricted experiments.¹⁰

(a) An individual or entity may not conduct a restricted experiment with a VS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the Administrator. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the Administrator and the HHS Secretary.

(b) *Restricted experiments:* (1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could

¹⁰For guidance, see the NIH publication, "NIH Guidelines for Research Involving Recombinant DNA Molecules." This document is available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

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compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD₅₀ <100 ng/kg body weight.

(c) The Administrator may revoke approval to conduct any of the experiments in paragraph (b) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(d) To apply for approval to conduct any of the experiments in paragraph (b) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

§ 121.14 Incident response.¹¹

(a) An individual or entity required to register under this part must develop and implement a written incident response plan.¹² The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

(c) The incident response plan must also contain the following information:

¹¹Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

¹²Technical assistance and guidance may be obtained by contacting APHIS.

(1) The name and contact information (e.g., home and work) for the individual or entity (e.g., responsible official, alternate responsible official(s), biosafety officer, etc.);

(2) The name and contact information for the building owner and/or manager, where applicable;

(3) The name and contact information for tenant offices, where applicable;

(4) The name and contact information for the physical security official for the building, where applicable;

(5) Personnel roles and lines of authority and communication;

(6) Planning and coordination with local emergency responders;

(7) Procedures to be followed by employees performing rescue or medical duties;

(8) Emergency medical treatment and first aid;

(9) A list of personal protective and emergency equipment, and their locations;

(10) Site security and control;

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge; and

(12) Decontamination procedures.

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

§ 121.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the Administrator or the HHS Secretary before he/she has such access. In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access by the Administrator or the HHS Secretary before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers,